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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,331	08/04/2003	Alan J. Polito	7035-0003.03	6774

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ROBINS & PASTERNAK
1731 EMBARCADERO ROAD
SUITE 230
PALO ALTO, CA 94303

EXAMINER	
HINES, JANA A	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,331	POLITO ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *98-116* is/are pending in the application.

4a) Of the above claim(s) *107-116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *98-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed June 17, 2005 has been entered. The examiner acknowledges the amendments to the specification. Claims 1-97 have been cancelled. Claims 98-100 have been amended. Claims 107-116 have been withdrawn from consideration. Claims 98-106 are under consideration in this office action.

Withdrawal of Objections and Rejections

2. The objection of claims 102-106 under 37 CFR 1.75(c) has been withdrawn in view of applicants amendments:

Response to Arguments

3. Applicant's arguments filed June 17, 2005 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The rejection of claims 98-106 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements is maintained for reasons already of record. The rejection was on the grounds that there is no structural relationship between the claimed apparatus and the apparatus' ability to detect and quantitate analyte. Applicants assert that the amendments should obviate

the rejection. However a housing and autostart means, that fail to even include a test strip, do not have the ability to detect and quantitate by the analysis of reflectance data gathered from one or more sectors of the test strip, which is not present. Applicants' amendments have not provided a cooperative structural relationship which account for the abilities of the apparatus. Therefore, applicants amendments are insufficient to overcome the rejection and the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 98-106 under 35 U.S.C. 102(b) as being anticipated by Zweig (US Patent 5,554,531) is maintained for reasons already of record. The rejection was on the grounds that the apparatus of Zweig (US Patent 5,554,531) teach an apparatus for conducting a lateral flow assay on a test strip for detection of an analyte in a sample comprising a housing; an autostart means; heating element; and test strip.

Applicants' assert that Zweig et al., lack any recitation of analysis of reflectance data from one or more sectors of the test strip. However the apparatus of Zweig et al., teach that monitoring of the analyte may occur by taking reflectance measurements (col. 9, lines 1-3). MPEP section 2123 teaches that patents are relevant as prior art for

all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). Therefore applicant's argument is not persuasive since the monitoring of Zweig et al., is not limited to only optical changes over time. Moreover, the disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Therefore, applicants' arguments are not persuasive since the prior art teaching using the same reflectance measurements.

It is also noted that the analysis of reflectance data from one or more sectors of the test strip does not require an additional structure to the apparatus; rather the language simply discloses that an algorithm is used to generate and detect the analyte. Thus, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, the prior art structure is capable of running such an algorithm, therefore Zweig et al., meet the limitations of the claims and applicants arguments are not persuasive.

Double Patenting

6. The double patenting rejection of claims 98-101 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,and 5-8 of U.S. Patent No.6,136,610 is maintained for reasons already of record. Applicants' assert that the apparatus of Polito et al., need not function in the way required by claim 98.

Applicants' assert that the apparatus of Polito et al., do not need to function in the way required by the instant claims. However, the issue is not whether the Polito et al., device needs to function in the same way, the issue is whether the claimed subject matter is patentably distinct from the subject matter claimed in a commonly owned

patent when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. In this case, the subject matter is not patentably distinct, and the mere allegation of a different function of the patented apparatus does not make the instant claims patentable distinct. See *Eli Lilly & Co. v. Barr Labs., Inc.,* 251 F.3d 955, 58 USPQ2d 1865 (Fed. Cir. 2001); *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000). The determination of the scope and content of a patent claim and the prior art relative to a claim in the application at issue is that both the apparatuses comprise the same components. The components of Polito et al., are capable of performing the intended use of executing instructions which generate a baseline from the lateral flow assay; quantifying the measurements and determining the presence of the analyte.

The patented apparatus comprises an apparatus which detects reflectance and which takes a baseline measurement of the lateral flow strip at measurement zones and takes analyte measurements. The software within the apparatus comprises executable instructions which determine the mathematical relationship by determining a relationship between the baseline measurement and the measured amounts. Both the instant claims and the claims of the US Patent are drawn to same elements, i.e., a housing, an autostart means, a heating element, and test strip components. The open language of the instant claims embraces the apparatus of US Patent 6,136,610. Therefore, the apparatus claimed within US Patent 6,136,610 comprises the same components which perform the same functions as those instantly recited within the claims. Thus the patented apparatus is capable of analyzing reflectance data from one or more sectors of

the test strip and the patented apparatus meets the limitations of the claims. Therefore, the conclusion of obviousness-type double patenting was made in light of these factual determinations, and the rejection is maintained and applicants' arguments are not persuasive.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 98-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for an apparatus comprising only a housing having a receptacle for retaining a test strip; and an autostart means has the ability to detect an analyte by analysis of reflectance data from one or more sectors of the test strip performed by the apparatus.

Applicant did not point to support in the specification for an apparatus comprising only a housing having a receptacle for retaining a test strip; and an autostart means has the ability to detect an analyte by analysis of reflectance data from one or more sectors of the test strip performed by the apparatus. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of an apparatus comprising only a housing and an autostart start means that has the ability to detect an analyte by analysis of reflectance data from one or more sectors of the test strip performed by the apparatus. Thus, there appears to be no teaching of the claimed apparatus. Applicant has pointed to page 29, lines 9-30 of the instant specification for support of the amendment, however page 29 teaches that an algorithm generates the baseline by approximating a relatively flat baseline in detection zones where the intensity of reflectance of the strip is variable with respect to the background of the strip. However the instantly claimed apparatus has no ability to detect the analyte or analyze the analyte for reflectance data from one or more sectors of the test strip performed by the apparatus. Thus, it appears that the entire specification appears to fail to recite support for the newly amended apparatus. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity of an apparatus comprising only a housing having a receptacle for retaining a test strip; and an autostart means has the ability to detect an analyte by analysis of reflectance data from one or more sectors of the test strip performed by the apparatus as recited by the amendments. Therefore, the claims incorporate new matter and are accordingly rejected.

8. Claims 98-106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 98 is drawn to an apparatus wherein the analyte is detected by analysis of reflectance data from one or more sectors of the test strip performed by the apparatus, however there is no test strip present. Therefore, it is unclear how the analysis of reflectance data from one or more sectors of the test strip can occur when the apparatus only has a receptacle for retaining a test strip and not an actual test strip.

b) Claim 100 is drawn to the detection of the analyte carried out by the apparatus to include the quantitation of the analyte. However it is unclear how an apparatus comprising only a housing and autostart means will carry out the detection of the analyte and quantitate the analyte since the apparatus fails to recite any structural features that are capable of detecting and quantitating analyte.

Claim Objections

9. Claim 100 is objected to because of the following informalities: Claim 100 is dependent upon claim 100. Appropriate correction is required.

Conclusion

10. No claims allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
August 25, 2005

L. F. S.
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600